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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LASSE WESSELTOFT MOGENSEN, GRETE KORNERUP, and MAGNUS WALTER GORANSSON

Appeal 2010-004597 Application 10/687,568 Technology Center 3700

Before STEFAN STAICOVICI, GAY ANN SPAHN, and MICHAEL C. ASTORINO, *Administrative Patent Judges*.

SPAHN, Administrative Patent Judge.

DECISION ON APPEAL

STATEMENT OF THE CASE

Lasse Wesseltoft Mogensen et al. (Appellants) appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 55, 57, 58, 66, 70, 71, and 73. Appellants cancelled claims 1-39 and 44-49. The Examiner indicated the allowability of claims 40-43, 50-54, 56, 61-65, 67, and 68 and

objected to claims 59, 60, 69, and 72 as being dependent upon a rejected base claim. We have jurisdiction under 35 U.S.C. \(\) 6(b).

The Invention

Claim 55, reproduced below, with italics added, is illustrative of the subject matter on appeal.

> An injector device assembly, comprising: an infusion set including a housing and a hollow cannula.

> > a molded device housing,

a cover member removably secured to said device housing, said cover member covering an end of said device housing.

a molded plunger movably received within said device housing for movement between an advanced position and a retracted position,

a lock for releasably locking said plunger in said retracted position, said device housing being manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger, and

a drive for urging said plunger from the retracted position towards said advanced position.

App. Br. 40.

Independent claim 66 recites an injector device assembly including "a molded device housing receiving at least a part of said infusion set, said part of said infusion set positioned removably from and within said device housing." App. Br. 44.

The Rejections

The following Examiner's rejections are before us for review.¹
Claims 55, 57, 66, 70, 71, and 73 are rejected under 35 U.S.C.

§ 102(b) as anticipated by Miskinyar (US 4,894,054, iss. Jan. 16, 1990).²
Ans. 3.

Claim 58 is rejected under 35 U.S.C. § 103(a) as unpatentable over Miskinyar and Teeple (US 5,807,316, iss. Sep. 15, 1998). Ans. 4.

SUMMARY OF DECISION

We REVERSE.

OPINION

Anticipation based upon Miskinyar

The Examiner finds that Miskinyar anticipates independent claims 55 and 66 by disclosing an injector device comprising: an infusion set, including a housing (ampoule 74) and a hollow cannula (needle 22); a molded device housing 10; a cover (protective cover 38 and frangible sterile tape 72); a plunger (ampoule member18); and the device housing 10 being manually deformable via the actuator button 33 to release the plunger 18. Ans. 3.

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¹ Claims 55-57, 60-64, 66, and 69-73 were finally rejected under 35 U.S.C. § 102(e) as anticipated by Safabash (US 6,293,925 B1, iss. Sep. 25, 2001) (Final. Rej. 2-3); however, the Examiner withdrew this rejection (Ans. 3-4). ² Claims 60 and 72 were finally rejected under this ground of rejection (Final Rej. 2), but the Examiner withdrew the rejection as to these claims (Ans. 3). ³ Claim 59 was finally rejected under this ground of rejection (Final Rej, 3), but the Examiner withdrew the rejection as to this claim (Ans. 4).

Independent Claim 55

Appellants contend that Miskinyar does not anticipate independent claim 55 for failing to disclose "a device housing manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger." App. Br. 26. Appellants note that the Examiner alleges Miskinyar's button 33 to be a part of the housing 10 and contend that even if this is true, Miskinyar does not disclose that the button 33 is deformable. *Id.* Appellants cite to Webster's Ninth New Collegiate Dictionary which defines the word "deform" as "to alter the shape of by stress." App. Br. 27. Appellants argue that Miskinyar does not disclose deforming or altering the shape of the button 33, but rather only discloses changing the position of the button 33. *Id.*

In response to Appellants' arguments, the Examiner alleges that the actuator button 33 is part of housing 10 and Appellants have no basis for their assertion that the button 33, which actually forms a top of the housing, is not part of the housing. Ans. 5. The Examiner also alleges that "[t]he button moves up and down, which makes it manually deformable from a first (up) to a second (down) position, relative to the rest of the housing. Thus, the housing (as a whole) changes shape or deforms." Id. Finally, the Examiner alleges that "[t]he button may be pushed at the sides to deploy the plunger." Id.

Miskinyar discloses a hypodermic medicinal injector or syringe device including a housing 10 having a central cavity 12. Col. 1, Il. 7-8 and col. 2, Il. 34-37. The central cavity 12 has an internal well 14 with a cylindrical wall 16 to slidably receive a cylindrically shaped ampoule member 18. Col. 2, Il. 37-40. The ampoule member 18 has a hypodermic

needle 22 extending through its undersurface and communicating with the medication chamber or ampoule 74 containing medication 78. Col. 2, Il. 40-43 and col. 3, Il. 50-53. An actuator button 33 in the top of the housing 10 is depressed in order for a hypodermic needle 22 to deliver medication 78 to a patient from the ampoule 74 within an internal ampoule chamber 24 of the ampoule member 18. Col. 2, Il. 56-58, col. 3, Il. 43, 52-53, and 60-63, and col. 4, Il. 14-22.

We agree with the Appellants that Miskinyar does not anticipate independent claim 55 for failing to teach "a device housing manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger." Like Appellants, we find that an ordinary and customary meaning of the term "deform" is "to alter the shape of by stress." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (10th Ed. 1997). In order to deliver a dose of medication 78 to a patient, Miskinyar's actuator button 33 is depressed and merely moves from its position shown in Figure 2 to its position shown in Figure 3, without undergoing any deformation. Although the button 33 changes position with respect to the housing 10, this does not result in a deformation or an alteration of the shape of by stress of either the button 33 or the housing 10.

Thus, neither Miskinyar's housing 10 nor actuator button 33 meet the claim language of being "manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of said plunger." In view of the foregoing, we do not sustain the Examiner's rejection of claims 55, 57, and 73 under 35 U.S.C. § 102(b) as anticipated by Miskinyar.

Independent Claim 66

Appellants contend "Miskinyar does not disclose that a part of an infusion set received by device housing is 'positioned removably from and within said device housing.'" App. Br. 29.

In response to Appellants' arguments, the Examiner indicates that the claim term "removably" is a term of capability so that Miskinyar's device only need be capable of performing the recited function of being removable, not disclosed as performing the function of being removed. Ans. 5. The Examiner suggests that Miskinyar's needle 22 "is capable of being removed by cutting, snapping, breaking, etc." *Id.* The Examiner notes that "there is nothing [in] the claims about the needle or cannula remaining in the patient or even being removable once inside the patient." Ans. 5-6.

We agree with Appellants that no part of Miskinyar's infusion set is capable of being positioned removably from and within the device housing. According to the Examiner, Miskinyar's infusion set includes a housing (ampoule 74) and a hollow cannula (needle 22). Ans. 3. Miskinyar discloses that the ampoule 74 is formed by an elastic balloon which is received in and sealed to the inner walls of the ampoule chamber 24. Col. 3, Il. 47-53. Thus, the ampoule 74 is not removable from the housing 10 in order to satisfy the claim language that a part of the infusion set is positioned removably from the device housing. In addition, as pointed out by Appellants, "Miskinyar discloses that hypodermic needle 22 is attached to ampoule member 18 since it moves with ampoule member 18 from the loaded position shown in [Figure] 2 to the released position of [Figure] 3." App. Br. 29. Thus, the needle 22 is not removable from the housing 10 in

order to satisfy the claim language that a part of the infusion set is positioned removably from the device housing.

In response to the Examiner's suggestion that Miskinyar's needle can be removed by cutting, snapping or breaking, Appellants argue that "[w]hile in general it might be acceptable practice in the medical field to use a needle to penetrate epidermis to inoculate a patient, inserting a needle, cutting it off, and leaving it in the patient would not be safe, sanitary, or intended." App. Br. 30. We agree. A person of ordinary skill in the art would not removably position Miskinyar's needle 22 with respect to the housing 10 by cutting, snapping, or breaking the needle 22 because this might leave a piece of the needle in the patient thereby possibly harming the patient.

Thus, since neither Miskinyar's ampoule 74 nor needle 22 is removable from the housing 10 and since a person of ordinary skill in the art would not cut, snap or brake the needle 22 to removably position it with respect to the housing 10, Miskinyar fails to satisfy claim 66's language of a part of the infusion set being positioned removably from the device housing. In view of the foregoing, we do not sustain the Examiner's rejection of claims 66, 70, and 71 under 35 U.S.C. § 102(b) as anticipated by Miskinyar.

Obviousness based on Miskinyar and Teeple

With respect to the rejection of claim 58, the addition of Teeple does not remedy the deficiency of Miskinyar as discussed above with respect to claim 55. Therefore, we do not sustain the Examiner's rejection of claim 58 under 35 U.S.C. § 103(a) as unpatentable over Miskinyar and Teeple.

DECISION

We reverse the Examiner's decision to reject claims 55, 57, 58, 66, 70, 71, and 73.

REVERSED

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